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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/466,035	12/17/1999	MATTI SALLBERG	930049.458C1	9697

27476 7590 08/11/2005

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/466,035

Applicant(s)

SALLBERG ET AL.

Examiner

Anne Marie S. Wehbe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 04 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 12, 13 and 26-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 12-13, and 26-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment filed on 5/6/05 have been entered. Claim 24 has been canceled. Claims 1-5, 12-13, and 26-30 are pending in the instant application. An action on the merits follows.

It is noted that those sections of Title 35, US code not included in this action can be found in the previous office action.

Information Disclosure Statement

Applicant's IDS filed on 5/6/05 has been considered by the examiner. An initialed copy is attached to this office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 30 depends on claim 1. Claim 1 has been amended to remove the limitation that the gene delivery vehicle can be a plasmid vector. The gene delivery vehicle of

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claim 1 is now selected from a group consisting of retroviral, alphaviral, parvoviral, or eukaryotic layered vectors. Thus, the limitation in claim 30 which states that the gene delivery vehicle is a plasmid vector conflicts with the limitations of claim 1. As such the metes and bounds of claim 30 cannot be determined.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 4, 24, 26, and 30 under 35 U.S.C. 102(a) as being anticipated by Fuller et al. (1996) J. Med. Primatol., Vol. 25, 236-241, is withdrawn in view of applicant's amendment to claim 1 which limits the methods to using gene delivery vehicles other than plasmid vectors.

Claim Rejections - 35 USC § 103

The rejection of claims 1-3, 5, 12-13, and 27-29 under 35 U.S.C. 103(a) as being unpatentable over WO 95/07994 (1995), hereafter referred to as Dubensky et al., in view of Hu et al. (1991) AIDS Res. Hum. Retrovir., Vol. 7 (7), 615-620 is maintained over amended claims **1-5, 12-13, and 26-30**. Please note that as claims 4 and 26 were inadvertently omitted from the rejection of record as set forth in the office action mailed on 11/17/04, this action has been made **non-final**.

Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant rejection for reasons of record as discussed in detail below.

The applicant argues that since Dubensky et al. does not teach the prime boost strategy taught by applicants and that Hu et al. does not teach using the particular vector systems claimed by applicants, improper hindsight reasoning was used to construct the rejection of record. In addition, the applicant argues that motivation for combining the teachings of the cited references was not provided, citing *In re Kotzab*. In regards to the argument that neither Dubensky et al. nor Hu et al. teach each element of the instant invention, it is noted that the test for combining references is not what the individual references themselves suggest, but rather what the combination of disclosures taken as a whole would have suggested to one of ordinary skill in the art. *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). For the purpose of combining references, those references need not explicitly suggest combining teachings, much less specific references. *In re Nilssen*, 7 USPQ2d 1500 (Fed. Cir. 1988). The office clearly stated that while Dubensky et al. teaches alphavirus vectors and layered eukaryotic vector initiation systems comprising sindbis, retrovirus or adeno-associated virus vectors capable of expressing a viral antigen, and the administration of alphavirus vectors or layered eukaryotic vector initiation systems capable of expressing a viral antigen to warm-blooded animals in order to generate an antigen-specific immune response, wherein the viral antigen is derived from HIV or hepatitis (see Dubensky et al., pages 8, and 33-40), Dubensky et al. only differs from the instant invention as claimed by failing to teach a prime-boost strategy of immunization. However, the rejection of record relies on Hu et al. for the missing teachings and further for the motivation to combine the teachings of Hu et al. with Dubensky et al. Specifically, the office has set forth that Hu et al. supplements Dubensky et al. by teaching that antibody responses against viral antigens can be increased by using a prime boost

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strategy where a subunit protein vaccine is administered either before or after the administration of a viral vector encoding the protein antigen (Hu et al., page 615 and page 617, Table 1). The rejection of record further identifies the specific motivation for combining the teachings of Hu with Dubensky as follows: the skilled artisan would have been motivated to use the prime-boost strategy taught by Hu et al. to induce immune responses against viral antigens based on the teachings of Hu et al. that boosting vector vaccines with subunit vaccines is more effective than immunization with vector alone. Thus, the rejection of record concludes that based on the motivation provided by Hu et al. for using a prime-boost strategy for immunization against viruses, it would have been *prima facie* obvious at the time of filing for the skilled artisan to supplement the immunization strategy using alphavirus vectors and layered eukaryotic initiation systems taught by Dubensky et al. by administering viral proteins prior to or subsequent to the administration of the vector. In view of the enhanced immune response observed by Hu et al. using the prime-boost strategy, the skilled artisan would have had a reasonable expectation of success in generating an immune response against a viral antigen by administering an alphavirus vector or layered eukaryotic initiation system capable of expressing a viral antigen either prior to or subsequent to the administration of viral protein. Thus, the rejection of record, clearly meets the standards in *In re Kotzab* for establishing a *prima facie* case of obviousness by particularly pointing out the reasons why the skilled artisan would have been motivated to combine the teachings of Hu et al. with those of Dubensky et al.

Further, in response to applicant's comments regarding the use of hindsight reasoning, it is noted that "[a]ny judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within

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the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper."

In re McLaughlin, 443 F2d. 1392, 170 USPQ 209, 212 (CCPA 1971). From the analysis of the rejection of record set forth above, it is clear that the rejection of record relies on the motivation provided by Hu et al. that prime-boost vaccination against viruses result in enhanced anti-viral immune responses over that observed with vector or subunit vaccination alone for combining the teachings of Hu et al. and Dubensky et al. and not applicant's disclosure. Therefore, the rejection of record is maintained.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

